AUG 14 2012

# 510(k) Summary

K_____

This summary of 510(k) summary information is being submitted in accordance with the requirements of 21 CFR § 878.4810.

Submission Date: August 1, 2011

**1. Submitter Information:** AEGIS Regulatory, Inc. - Robert T. Wagner
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Knoxville, TN 37922
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**For Manufacturer:** Silver Bay, LLC d/b/a Quasar Bio-Technologies
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Sarasota, FL 34231
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Email: peter@quasarbiotech.com

**2. General Information**

2.1 Classification Name: Wrinkle Reduction Device

2.2 Common/Usual Name: Light Therapy System, Quasar Calypso C100

2.3 Proprietary Names: Quasar Calypso C100 Wrinkle Reduction Device

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Codes: OHS

**3. Device Description:**

The Silver Bay, Quasar Calypso, C100 Anti-Wrinkle device consists of a collection of red and near infrared diodes (LEDs), packaged in a compact hand held device. The device has a head containing the LED array and an on/off switch.
The device is made of ABS plastic with clear polycarbonate lenses covering the LED light source. The Quasar Calypso C100 uses a 12 volt wall mount power supply.

The C100 light delivery system used for applying therapy for the use in the treatment of periorbital wrinkles, by emitting at least 65 mW/cm$^2$ of red and near infrared (610nm to 850nm) light via an electric light emitting diodes [LEDs] energy source. There are 20 red LEDs and 20 infrared LEDs in the head. The device is not intended for ocular applications or direct eye exposure.

**4. Indications / Intended Use:**

The Quasar Calypso C100 is an Over-The-Counter handheld device intended to emit energy in the red/IR spectrum, specifically indicated for use in the treatment of periorbital wrinkles.

Rx or OTC:

The C100 is an Over the Counter (OTC) device. The labeling, instructions, and User Operations (21 CFR § 801.60 and 61), are designed for layman understanding and use. The predicate device is OTC.

**5. Predicate Device:**

This device is substantially equivalent to the following predicate devices, which are currently in safe and effective commerce:

1. K101190 – Light for Wrinkles (Led Intellectual Properties, LLC)

**Predicate Chart**

| Device | Light for Wrinkles<br>AAL OCT (K101190)<br>LED Intellectual Properties LLC<br>A Predicate Device | C100<br>Quasar Bio-Tech Inc<br>K112362<br>This Submission |
|---|---|---|
| **Indications** | The Light for Wrinkles is an Over-The-Counter handheld device intended for use in the treatment of periorbital wrinkles. The target patient population for the AAL OCT is persons with periorbital wrinkles. It is designed for home use. | The C100 is intended to emit energy in the red and IR region of the spectrum, specifically indicated for use in the treatment of periorbital wrinkles. The target patient population for the C100 is the same as the predicate devices. Like the predicate devices, the C100 is designed |

| Device | Light for Wrinkles<br><br>AAL OCT (K101190)<br>LED Intellectual Properties LLC<br><br>A Predicate Device | C100<br><br>Quasar Bio-Tech Inc<br><br>K112362<br><br>This Submission |
|---|---|---|
| | | for home use. |
| **Handheld** | Yes | Yes |
| **Wavelengths** | 605nm, 630nm, 660nm, 855nm | 610, 630 and 660, 850nm |
| **Modes** | On/Off | On/Off |
| **IR power source** | LEDs | LEDs |
| **Visible light LEDs** | Yes | Yes |
| **Waveform** | Constant | Constant |
| **Energy Source** | 70 LED's over 27 sq. cm. | 40 LEDs. Over 20 sq. cm |
| **Energy Level** | 65 mW total | 65 mW total |
| **Power Supply** | 115VAC Electric Outlet Power Supply | 115VAC Electric Outlet Power Supply |
| **Treatment Time** | 3 minutes daily, minimum 5 days per week | 3 minutes daily, minimum 5 days per week |
| **Target Population** | Individuals with periorbital lines and wrinkles. | Individuals with periorbital lines and wrinkles. |
| **Location for Use** | OTC | OTC |

Summary of the technological characteristics of the device compared to predicate device:

The C100 and the above referenced predicate, Light for Wrinkles device, are Over the Counter Devices used to treat wrinkles as defined in 21 CFR § 878.4810. These devices utilize red and infrared diodes from 610 to 850 nm to provide narrow bands of light energy to treat wrinkles. The performance achieved by these devices is similar with equal power output. The devices are handheld, and intended to be placed directly on the skin or held just over the skin. They are manufactured out of similar materials. Based upon comparison to the predicate device, the C100 has the same intended uses, with similar technological characteristics as the predicate device. The system performs as intended and does not raise any new safety or effectiveness issues.

**6. Biocompatibility:**

The only patient contact material in the C100 is the light head and body of the device.

The light head in contact with the face is Polycarbonate and the body is constructed of ABS plastic, the same materials used in the predicate device. The biocompatibility of these materials are well known and considered safe when in contact with healthy skin. A review of the Biocompatibility decision is shown on the "General Program Memorandum- #G95-1, Attachment C, Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s."

The conclusion is that the C100 m does not raise any new safety issues.

**7. Performance Testing and Standards:**

These devices have been tested under and are in compliance with performance standards that have been established for such devices under Section 878 of the Federal Food, Drug, and Cosmetics Act. All electrical and radiological products made by the applicant have been OSHA/NRTL listed, and have received constituent marks.

The device has been tested and is in conformity with IEC/EN 60601-1, IEC/ EN 60601-1-2, IEC 62471 Standards.

**8. Statement of Safety and Effectiveness:**

The information in this 510(k) submission was used to support the safety and effectiveness of this device with respect to its cited predicates.

**9. Substantial Equivalence Discussion**

After an analysis of the safety, indications, intended uses,

performance, features, design materials, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no

significant differences exist between the device and the predicates listed in Section 5 Therefore substantial equivalency is requested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Silver Bay, LLC
% Aegis Regulatory, Incorporated
Mr. Robert T. Wagner
CEO
1131 Anthem View Lane
Knoxville, Tennessee 37922

AUG 14 2012

Re: K112362
Trade/Device Name: Quasar C100 Wrinkle Reduction Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: August 13, 2012
Received: August 13, 2012

Dear Mr. Wagner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

510(k) Number: K112362

Device Name: Quasar C100 Wrinkle Reduction Device

Indications for Use:

The Quasar C100 Wrinkle Reduction Device is intended to emit energy in the red and IR region of the spectrum, specifically indicated for the treatment of periorbital wrinkles.

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

OR

Prescription Use ____
(Per 21 CFR 801.109)

Over-The-Counter Use__X___
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112362